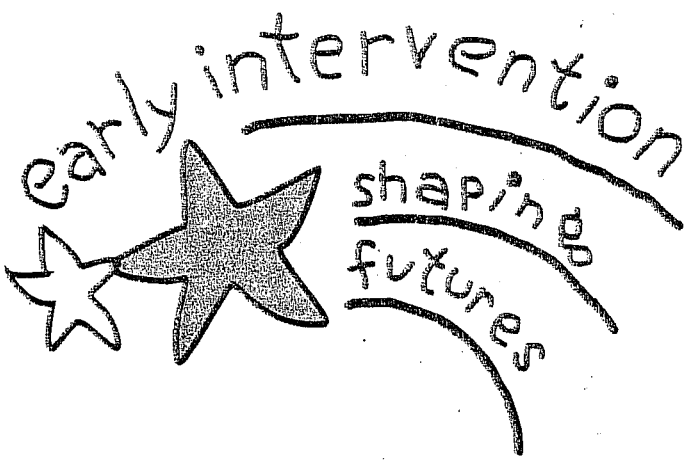
EXHIBIT 7

CLINICAL PRACTICE GUIDELINE

The Guideline Technical Report

AUTISM / PERVASIVE DEVELOPMENTAL DISORDERS

ASSESSMENT AND INTERVENTION FOR YOUNG CHILDREN (AGE 0-3 YEARS)



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EARLY INTERVENTION PROGRAM

Topics covered in this section

This section on behavioral and educational approaches for children with autism is divided into the following six parts:

Part 1 – Intensive behavioral and educational intervention programs

Part 2 – Basic principles of specific behavioral intervention techniques

Part 3 – Behavioral and educational intervention techniques for maladaptive behaviors

Part 4 – Behavioral and educational intervention techniques to improve communication

Part 5 – Behavioral and educational intervention techniques to improve social interactions

Part 6 – Parent training as part of behavioral and educational programs

1. INTENSIVE BEHAVIORAL AND EDUCATIONAL INTERVENTION PROGRAMS

a. Guideline Recommendations

[A] = Strong evidence; [B] = Moderate evidence; [C] = Limited evidence; [D1] = Panel opinion (information did not meet criteria for evidence); [D2] = Panel opinion (literature not systematically reviewed). *(See p. I-21.)*

Using principles of applied behavioral analysis for interventions

(1) It is recommended that principles of applied behavior analysis (ABA) and behavior intervention strategies be included as an important element of any intervention program for young children with autism. [A]

Frequency, intensity, and duration of intervention

(2) It is recommended that intensive behavioral programs include as a minimum, approximately 20 hours per week of individualized behavioral intervention using applied behavioral analysis techniques (not including time spent by parents). [A]

(3) It is recommended that the precise number of hours of behavioral intervention vary depending on a variety of child and family characteristics. Considerations in determining the frequency and intensity of intervention include age, severity of autistic symptoms, rate of progress, other health considerations, tolerance of the child for the intervention, and family participation. [A]

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(4) In deciding upon the frequency and intensity of a behavioral intervention, it is important to recognize that:

- ◊ In the studies reviewed, effective interventions based on ABA techniques used between 18 and 40 hours per week of intensive behavioral intervention by a therapist trained in this method.
- ◊ Based on the available scientific evidence, it is not possible to accurately predict the optimal number of hours that will be effective for any given child. [A]

- The four studies meeting criteria for evidence about efficacy all included some children under 3, but no studies looked specifically at this age group.
- None of the four studies that met criteria for efficacy used random assignment of the children to groups (such as to the group receiving intensive behavioral intervention versus the group receiving a comparison intervention). It has been argued that the method for group assignment probably did not bias the results.
- In all cases the authors analyzed baseline data on subjects to see if the groups were equivalent in important variables. Most authors concluded that such analyses found no systematic bias in the assignment of subjects to the intervention or comparison group. However, several critics (Foxx, 1993; Kazdin, 1993; Schopler, 1989) of these studies cite the lack of random assignment as an important reason to use caution in uncritically accepting the findings of these studies.
- Three of the four studies which met criteria for efficacy had assessment of outcomes by observers blinded to (unaware of) group assignment, and the remaining study used outcome observers blinded to the purpose of the study.
- Of the four studies that met criteria for efficacy, information documenting actual number of intervention hours delivered was reported in two studies (Birnbrauer and Leach, 1993; Sheinkopf and Siegel, 1998).

Results of the studies reviewed

- In all of the four studies that met criteria for efficacy, children who received intensive behavioral interventions showed greater improvement than children in the control groups (who received less intensive behavioral interventions, another type of intervention, or no intervention).
- In each of the studies reviewed, the behavioral interventions were part of a comprehensive program. Therefore, it is not possible to separate out the extent to which improvements in a child's behavior were due to the intensity of the intervention or to some other aspects of the program such as curriculum content.
- In general, children with higher levels of functioning (such as higher baseline mental age) had better outcomes.
- Several of the studies reviewed provided evidence that intensive behavioral intervention programs can be successful without the use of physical aversives.

Frequency, intensity, and duration of the interventions

- Considering all four studies together, it is possible to draw the following conclusions about how the intensity and frequency of an intensive behavioral intervention relates to the amount of gain achieved by young children with autism.
- The research evidence reviewed found that children who received approximately 20 to 40 hours a week of an intensive behavioral intervention program had significantly greater improvement than children in the control groups.

- Some data suggest that, within the range of 20 to 40 hours per week, a higher number of hours may result in better outcomes. The study described by Lovaas (1987) and by McEachin, (1993) used an average of 40 hours a week and reported the best long-term outcomes of all the studies reviewed. However, the effect of the number of hours per week cannot be separated from effects of other aspects of the total program.
- The study by Sheinkopf and Seigel (1998) found overall IQ gains in children receiving intensive behavioral intervention, but among these children there was no significant correlation between the total number of hours of individual behavioral therapy and amount of IQ gain. A possible reason for this is that the number of hours of therapy provided in a program frequently varies depending on the child's response to therapy. When a child improves, it is common to cut back on hours of individual one-to-one therapy and increase time in social or group activities, which could bias the results since children who do not respond may tend to get more one-to-one therapy than do children who improve.

d. Information about Harms and Costs

The panel found no evidence of any direct physical harms associated with the use of intensive behavioral intervention methods for young children with autism.

In the programs which were found to be effective, the intensity of therapy provided directly by professional and paraprofessional therapists varied between 20 to 40 hours per week. In most of these programs, the precise number of hours of therapy provided per week varied between children based on a variety of factors. In addition, as the child progressed and became more functionally independent, the amount of direct therapy was generally decreased. In programs found to be effective, professionals spent significant amounts of time supervising paraprofessionals and others working with the child. Time was also devoted to regular parent conferences.

None of the studies reviewed proposed using a finite period of intervention. The duration of therapy also depended upon the particular child's progress in the intervention program. However, most of the successful programs described used at least two years of intensive behavioral interventions for children with autism. In the only study that gave long-term outcome data, some children had been in the intensive program for much longer than two years.

The direct costs for an intensive behavioral intervention program depend primarily on the following factors: (1) the cost of staff time required by professionals and paraprofessionals (including time for coordination and supervision of staff) and (2) costs for materials and for facilities (if the program is center-based). The indirect costs for such a program include time spent by the family members participating in the intervention program.

GUIDELINE VERSIONS

There are three versions of each clinical practice guideline published by the Department of Health. All versions of the guideline contain the same basic recommendations specific to the assessment and intervention methods evaluated by the guideline panel, but with different levels of detail describing the methods and the evidence that supports the recommendations.

The three versions are:

The Clinical Practice Guideline: Report of the Recommendations

- full text of all the recommendations
- background information
- summary of the supporting evidence

Quick Reference Guide

- summary of major recommendations
- summary of background information

The Guideline Technical Report

- full text of all the recommendations
- background information
- full report of the research process and the evidence reviewed

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